

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Patent of : Atty Docket No. 0380-P00633US3  
Roger P. EKINS : Confirmation No: 8971  
U.S. Patent No. 5,807,755 :  
Issued: September 15, 1998 :  
For: DETERMIANTION OF AMBIENT :  
CONCENTRATIONS OF SEVERAL :  
ANALYTES :  
:

**REQUEST FOR A CERTIFICATE OF CORRECTION  
UNDER 37 C.F.R. §1.322(a)**

A Certificate of Correction is hereby requested for the above-identified patent. The error is as follows:

Column 1, lines 41-44, the equation, in part, was incorrectly printed as "K<sub>ab</sub>[H]<sup>2</sup>". The superscript 2 (2) should not appear in the equation, as the "2" was a page number. See attached copy of PCT/GB88/00649, on which this U.S. national stage application is based.

Based on our records, the mistake was made by the Patent and Trademark Office. Thus, it is believed by the undersigned attorney that no fee is required under 37 C.F.R. §1.322(a). In the event that any fee is required in connection with this submission, the Commissioner is authorized to charge such fee to the account of the undersigned attorneys, Account No. 04-1406.

We are enclosing Certificate of Correction Form PTO/SB/44 listing the errors made by the Patent and Trademark Office in printing the above-identified patent which should be corrected.

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Enclosure: Form PTO/SB/44

WO 89/01157

PCT/GB88/00649

$$\frac{Ab}{Ab_0} = \frac{K_{ab}[H]}{1 + K_{ab}[H]}$$

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where  $K_{ab}$  (hereinafter referred to as  $K$ ) is the equilibrium constant for the binding of the analyte to the binding sites and is a constant for a given analyte and binding agent at any one temperature. This constant is generally known as the affinity constant, especially when the binding agent is an antibody, for example a monoclonal antibody.

The concept of using only a trace amount of binding agent is contrary to generally recommended practice in the field of immunoassay and immunometric techniques. For example, in such a well-known work as "Methods in Investigative and Diagnostic Endocrinology", ed. S.A. Benson and R.S. Yallow, 1973 at pages 111-116, it is proposed that in the performance of a competitive immunoassay maximum sensitivity of the assay is achieved if the proportion of the "tracer" analyte that is bound approximates to 50%. In order to achieve such a high degree of binding of the analyte the theory of Benson and Yallow, to this day generally accepted by other workers in the field, requires that the concentration of binding agent (or, strictly speaking, of binding sites, each molecule of binding agent conventionally having one or at most two binding sites) must be greater than or equal to the reciprocal of the equilibrium constant ( $K$ ) of the binding agent for the analyte, i.e.  $[Ab] \geq 1/K$ . For a sample of volume  $V$  the total amount of binding agent (or binding sites) must therefore be greater than or equal to  $V/K$ . A binding agent which is a monoclonal antibody may, for example, have an equilibrium constant ( $K$ ) which is of the order of  $10^{11}$  litres/mole for the specific antigen to which it binds. Thus, under the above generally accepted practice, a binding agent (or site) concentration of the order of  $10^{-11}$  mole/litre or more is required for binding agents of such an equilibrium constant and, with fluid sample volumes of

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CERTIFICATE OF CORRECTION**Page 1 of 1

PATENT NO. : 5,807,755

APPLICATION NO.: 08/447,820

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INVENTOR(S) : Roger P. Ekins

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, lines 41-45, delete the equation and insert the following:

$$\frac{Ab}{Ab_o} = \frac{K_{ab}[H]}{1 - K_{ab}[H]}$$

**MAILING ADDRESS OF SENDER (Please do not use customer number below):**

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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.